Attorney Docket No.: 05033.0002.CPUS02

Application No.: 10/650,057

THE AMENDMENTS

In the Claims:

- 1. (Currently Amended) A method for detecting cervical carcinomas, cervical intraepithelial neoplasms or cervical carcinomas in situ in a human subject, the method comprising the steps of:
 - (a) obtaining a cervical body sample from the human subject,
 - (b) solubilizing the cervical body sample in an aqueous lysis buffer comprising 0.1-1% SDS, and
- (c) reacting the solubilized cervical sample in the aqueous lysis buffer comprising 0.1-1% SDS with an antibody against cyclin dependent kinase inhibitor p16, and
- (d) determining the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample by comparing the level of cyclin dependent kinase inhibitor p16 within said solubilized cervical sample with the level present in a solubilized healthy human cervical sample, wherein <u>cervical carcinomas</u>, cervical intraepithelial neoplasms or cervical carcinomas in situ in the human subject are detected if overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined.
- 2. (Original) The method according to Claim 1, wherein the level of cyclin dependent kinase inhibitor p16 in the healthy human cervical body sample is provided as a predetermined value to set up a threshold for the detection procedure.
- 3. (Original) The method according to Claim 1, wherein the level of cyclin dependent kinase inhibitor p16 in a healthy human cervical sample is determined from a standardized sample solution, or from a representative number of healthy human cervical samples.
- 4. (Previously Presented) The method according to Claim 3, wherein the determination of the level of cyclin dependent kinase inhibitor p16 in a healthy human cervical sample is carried out:
 - a. in the course of the detection procedure,
 - b. upon calibration of the detection system,

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- c. once for each lot of detection reagents, or
- d. as a standard value for the detection method.
- 5. (Original) The method according to Claim 1, wherein the cervical body sample is swab, smear, aspirate, biopsy, preserved cytological specimen, histological specimen, fixed cell preparation or fixed tissue preparation.
- 6. (Original) The method according to Claim 1, wherein the cervical body sample is solubilized
 - a. immediately after obtaining the sample,
 - b. after storage and/or transport in a storage buffer, or
 - c. after transport in a transportation buffer.
- 7-19. (Cancelled)
- 20. (Previously Presented) The method according to Claim 1, wherein the lysis buffer further comprises one or more additional non-ionic or anionic detergents.
- 21. (Previously Presented) The method according to Claim 1, wherein the lysis buffer further comprises a proteinase inhibitor.
- 22. (Cancelled)
- 23. (Previously Presented) The method according to Claim 1, wherein the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined by an ELISA.
- 24. (Previously Presented) The method according to Claim 1, wherein the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined by a lateral flow assay.
- 25. (Previously Presented) The method according to Claim 1, wherein the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined by an immunological assay selected from the group consisting of EIA, ELISA, RIA, FIA, and lateral flow assay.

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26. (Previously Presented) The method according to Claim 20, wherein at least one of said non-ionic detergents is t-octylphenoxypolyethoxyethanol.

- 27. (Previously Presented) The method according to Claim 1, wherein said aqueous lysis buffer comprises 0.1% SDS.
- 28. (Previously Presented) The method according to Claim 1, wherein said aqueous lysis buffer comprises 0.4% SDS.